REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of Claims

Claims 1, 3-5, 7-12, and 25-36 are currently pending in the application.

II. Withdrawn Objections and Rejections

Withdrawn Objections and Rejections

The previous Objections to the Specification, Double Patenting Rejections and Claim Rejections under 35 USC § 112 are not maintained by the Examiner in light of the applicant's arguments and change in status of 10/634,199 and therefore are considered to be withdrawn.

III. Pending Rejections

Claim Rejections – 35 USC § 103

The rejection of Claims 1, 3-5, 7-12 and 29-36 under 35 U.S.C. 103(a) as allegedly being unpatentable over Athwal et al. (WO01/94585) in view of Relton (WO97/45140) as is evidenced by the U.S. Pat. No. 6,171,586 is maintained.

The Examiner alleges the buffer formulation taught by the '140 publication is suitable for stabilizing antibody formulation of Fab fragments, bispecific antibodies (p. 4, line 26, in particular) or modified antibodies as is evidenced in the '586 patent. The Examiner contends the formulation taught by the '140 publication in stabilizing an antibody and the claimed antibody formulation are identical. Thus, the antibody

formulation being stable 25°C for at least twelve weeks is an expected property of the buffer formulation containing the antibody.

Applicant respectfully maintains that the Examiner has failed to establish a *prima facie* case of obviousness.

The Examiner alleges that the formulations taught in Example 4 of the WO97/45140 publication are identical to the presently claimed invention.

Applicant reiterates that this is factually incorrect for several reasons.

1) The Examiner states that '*the claimed stabilizing formulation requires a buffer maintaining pH of 3.5-6 (acetate), tonicifying amount of salt (NaCl) as in claims 1, 10, 12 and 29*'. It is respectfully submitted that the pending Claims 1, 3-5, 7-11 do **not** require a salt therefore they are **not identical** to the formulation as disclosed in Example 4 of '140.

2) Example 4 of '140 requires Polysorbate 80. None of the pending claims require Polysorbate 80. It is respectfully submitted that the pending Claims do **not** require Polysorbate 80 therefore they are **not identical** to the formulation as disclosed in Example 4 of '140.

3) The Examiner alleges that the preparation taught by the '140 publication is '*suitable for stabilizing antibody formulation of Fab fragments and bispecific antibodies*' and refers to page 4 line 26 of '140 reference. However, '140 is directed to methods of preparing a high concentration antibody preparation and the section referred to by the Examiner states "*the invention . . . extends to a preparation of Fab fragments and bispecific antibodies*". Regardless, of the components disclosed in '140 there is no inference that the preparation is suitable as a stable formulation and there is no stability data presented in the '140 application let alone that the formulation is stable for at least twelve weeks at 25°C. It is respectfully submitted that the pending Claims require that the formulation is stable for twelve weeks at 25°C therefore they are **not identical** to the formulation as disclosed in Example 4 of '140.

4) There is no mention of modified antibodies in the '140 application.

In an attempt to overcome the deficiencies of the '140 application with respect to modified antibodies the Examiner relies on WO01/94585 to teach CDP870, which is a nonproteinaceous polymer modified antibody. However, the Examiner has failed to factually establish that the formulation of '140 is suitable for extended stabilization of antibodies in general and any extension to modified antibodies is baseless.

The teachings of US 6,171,586 also fail to overcome the shortcomings of '140. The Examiner relies on '586 to allegedly teach stable formulations of modified antibodies. As the Examiner clearly admits the only modified antibodies taught by '586 are heteroconjugated antibodies such as biotin or avidin and thionitrobenzoate. '586 does not teach or disclose an antibody fragment modified by the covalently attachment of at least one nonproteinaceous polymer. Furthermore, the '586 formulations require additional excipients (i.e. surfactant and polyol) and there is no room temperature stability data beyond one month. To the contrary the data of '586 shows and the patentee concludes that the formulations were only stable at 30°C for one month (Figure 19 and description of Figure 19 on column 4 lines 35-44). Therefore, the Examiner's statement that "*the antibody formulation being stable 25°C for at least twelve weeks is an expected property of the buffer formulation containing the antibody*" is factually inconsistent with the teachings of '586 and is contrary to the patentee's own conclusion.

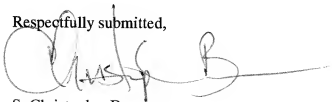
Consequently, one of skill in the art would not have been motivated to combine the teachings of the three publications believing to have a reasonable expectation of sources in producing applicants' temperature stable antibody-nonproteinaceous polymer conjugate formulation as presently claimed. There is no motivation to combine the references to achieve the presently claimed stable modified antibody formulation where the prior art teaches away. Therefore, applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness.

Applicants respectfully request the Examiner to reconsider the rejection of claims 1, 3-5, 7-12 and 29-32 and withdraw the rejection under 35 U.S.C. §103 (a).

Conclusion

Applicants respectfully submits that all the grounds for rejection of the pending claims have now been overcome and that all the claims are now in condition for allowance. Therefore, swift passage of the application and claims to issue is respectfully requested. In the event that the Examiner wishes to discuss any aspect of this response for purposes of advancing the prosecution, please contact the undersigned representative at the telephone number provided below.

Respectfully submitted,



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